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U.S. Congress. House.

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Food, Drugs, and
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Report

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74TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 2755

AUG - 6 1936

FOOD, DRUGS, AND COSMETIC ACT

MAY 22, 1936.—Referred to the Committee of the Whole House on the State of the Union

Mr. CHAPMAN, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Interstate and Foreign Commerce, to whom was referred the act (S. 5) to prevent the adulteration, misbranding, and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, report favorably thereon with an amendment and recommend that the act do pass.

The committee amendment strikes out all of the Senate bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

INTRODUCTORY STATEMENT

THE PRESIDENT'S MESSAGE

On March 22, 1935, the President sent the following message to the Congress:

To the Congress of the United States:

Every enterprise in the United States should be able to adhere to the simple principle of honesty without fear of penalty on that account. Honesty ought to be the best policy not only for one individual, or one enterprise, but for every individual and every enterprise in the Nation. In one field of endeavor there is an obvious means to this end which has been too long neglected: The setting up and careful enforcement of standards of identity and quality for the foods we eat and the drugs we use, together with the strict exclusion from our markets of harmful or adulterated products.

The honor of the producers in a country ought to be the invariable ingredient of the products produced in it. The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearance with inward integrity. In such a situation as has

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grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently and producers are handicapped in any attempt to maintain higher standards. Only the scientific and disinterested activity of government can protect this honor of our producers and provide the possibility of discriminating choice to our consumers.

These principles have long been those on which we have founded public policy. But we have fallen behind in their practical application. No comprehensive attempt at reform in the regulation of commerce in food and drugs has been made since 1906. I need not point out to you how much has happened since that time in the invention of new things and their general adoption, as well as in the increase of advertising appeals. Because of these changes loopholes have appeared in the old law which have made abuses easy.

It is time to make practical improvements. A measure is needed which will extend the controls formerly applicable only to labels to advertising also; which will extend protection to the trade in cosmetics; which will provide for a cooperative method of setting standards and for a system of inspection and enforcement to reassure consumers grown hesitant and doubtful; and which will provide for a necessary flexibility in administration as products and conditions change.

I understand this subject has been studied and discussed for the last 2 years and that full information is in the possession of the Congress.

No honest enterpriser need fear that because of the passage of such a measure he will be unfairly treated. He would be asked to do no more than he now holds himself out to do. It would merely make certain that those who are less scrupulous than I know most of our producers to be, cannot force their more honest competitors into dishonorable ways.

The great majority of those engaged in the trade in food and drugs do not need regulation. They observe the spirit as well as the letter of existing law. Present legislation ought to be directed primarily toward a small minority of evaders and chiselers. At the same time even-handed regulation will not only outlaw the bad practices of the few but will also protect the many from unscrupulous competition. It will, besides, provide a bulwark of consumer confidence throughout the business world.

It is my hope that such legislation may be enacted at this session of the Congress.

FRANKLIN D. ROOSEVELT.

THE WHITE HOUSE,
March 22, 1935.

GENERAL PURPOSES

This act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906, as amended (U. S. C., title 21, secs. 1–15). That act is popularly known as the "Wiley pure food law" because that great pioneer in pure food and drug legislation, Dr. Harvey W. Wiley, led the fight for its enactment.

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. In considering the measure the committee had before it a host of exhibits and examples of abuses of the consumer's health and pocketbook, against which there is now no effective restriction or no restriction at all. Among these were the following:

Worthless drugs sold for serious diseases, with accompanying death certificates showing death of users from those same diseases and evidence that their health might have been restored or lives prolonged through rational treatment.

Instances of deaths from powerful drugs bearing truthful labels, but where the directions for use called for too large or too frequent dosage or other improper use.

Fed Oct. 12, 1926

Potent drugs with labels that gave no warning against their probable misuse, with evidence of severe sickness and death caused by them.

Deadly drugs intended for reducing purposes or otherwise to affect the structure or function of the body, which do not fall within the narrow definition of drug in the present law.

Dangerous and worthless therapeutic devices.

Cosmetics that have caused deaths, blindness, and other bodily injury.

Poisonous foods in which the poison was a natural one and not added.

Foods contaminated with dangerous disease organisms for which no adequate control exists.

Confectionery containing metallic trinkets, with X-rays showing the trinkets lodged in the windpipes of children.

Uninformatively labeled infant and invalid foods.

Debased and cheapened foods sold under distinctive names, protected by the distinctive name proviso in the present law.

Deceptive advertising of food, drugs, therapeutic devices, and cosmetics, resulting in innumerable abuses of consumer welfare.

These and many other illustrations before the committee demonstrate conclusively the need for prompt enactment of a measure to tighten up the provisions of the present law and extend its scope beyond its present limitations.

The committee approached the problem in a practical way. It has undertaken to provide a measure which will be an effective control for existing abuses and at the same time will impose no limitation, embarrassment, or hardship on honest industrial enterprise. The measure asks no more of honest business than what honest business now holds itself out to do. It merely sets up checks against the small but unscrupulous minority who have not chosen to observe the underlying principles of the old Wiley law and have taken advantage of its limitations to mulct the public and embarrass honest competitors.

IMPROVEMENTS OVER EXISTING LAW

The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception; it extends the scope of the law to include false advertising, cosmetics, therapeutic devices, and certain drugs that now escape regulation; and it strengthens the procedural provisions to make more certain the accomplishment of its purpose.

The principal respects in which the measure differs from the present law are:

False advertising of food, drugs, devices, and cosmetics is brought under regulation.

The adulteration and misbranding of cosmetics is prohibited.

Therapeutic devices are brought under control.

Drugs intended for diagnosing illness or for remedying underweight or overweight, or for otherwise affecting bodily structure or function are subjected to regulation.

Reasonable sanitation is required in the production of foods, drugs, and cosmetics.

Foods that are dangerous because of naturally contained poisons rather than added poisons are brought under regulation. The addition of poison to foods is prohibited except where such addition is necessary or cannot be avoided; and in such cases tolerances are provided limiting the amount of added poison to the extent necessary to safeguard the public health.

Where the other provisions of the measure are not effective to control danger to health arising from bacterial contamination of food, temporary license restrictions can be imposed until the difficulty is corrected.

Definitions and standards of identity are provided under which the integrity of food products can be effectively maintained.

Informative labeling of foods as to quality and composition is required for the information and guidance of consumers. Special emphasis is placed on the informative labeling for infant and invalid food.

The distinctive name proviso of the present law under which many debased and cheapened foods have escaped control is eliminated.

Informative labeling of distilled liquors is required to the extent that the same requirements are not imposed under the Federal Alcohol Administration Act.

The fraud joker, under which proceedings could be brought against falsely labeled patent medicines only upon evidence to prove that the manufacturer knew his labels were false, is eliminated.

Control is set up for drugs which are dangerous to health when taken in the dosage and with the frequency prescribed by the manufacturer in the labeling and advertising.

Habit-forming drugs must be labeled with warnings that they are habit forming.

Potent drugs liable to be misused must bear label warnings against probable misuse.

Special safeguards are set up for packaging and labeling deteriorating drugs.

Antiseptics must possess germ-killing power.

Authority is provided for inspection of factories making interstate shipments, without which the law could not be effectively enforced.

Carriers are required to make available for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established.

Increased penalties are provided for violations.

Injunction proceedings are authorized against repetitious offenses.

These and other less important provisions are contained in the bill to make the measure effective for consumer protection without imposing unnecessary burdens on industry.

Explanation of Certain Changes Made by the Committee

The Senate committee report explained the provisions of the bill in detail, and it is not believed to be necessary to repeat this explanation here.

Most of the changes from the Senate bill made by this committee are self-explanatory, but the following explanation is given with regard to some of them in order to avoid possible misunderstanding as to the intention of the committee:

Section 201 (b): The words "and not for the regulation of the legalized practice of the healing art" were omitted from the definition of drug because the committee was of the opinion that these words were unnecessary and if left in the act would merely cause confusion. The bill does not undertake to regulate the practice of the healing art. The inclusion of the words would merely give an excuse, in every proceeding involving a drug, for the claimant or the defendant to raise the question as to whether the practice of the healing art was being regulated in the particular instance. In the reference to the United States Pharmacopœia, the Homeopathic Pharmacopœia, and the National Formulary, the committee has added the word "official" before each reference in order that this reference will be understood to be to the current edition of the particular compendium. Each such compendium comes out periodically and the new issue will be the official issue.

Section 201 (c): The same words are stricken from this subsection as are stricken from subsection (b) and the same reasons for the action apply.

Section 201 (d): This paragraph defines the term "cosmetic" and the changes made by this committee are not changes of substance but are changes for the purpose of clarity, with one exception, namely, that the exception in the case of household cleansers is omitted as being surplusage.

Section 301 (a): It will be noted that the references to sections 701 and 703 are stricken out in this paragraph as well as throughout the bill. These references were stricken out because it was not necessary to refer to the sections, and in view of the problem of changing section numbers due to the striking out of certain sections in the bill it was deemed more convenient to omit the references to section 701 and section 703.

Section 302 (e): In this paragraph the words "it fails to bear" were stricken out and the words "unless it bears" were substituted therefor in order to make it more clear that both of the requirements specified are intended to apply.

Section 302 (k): In this paragraph the words "which is not prohibited by section 301" were omitted as being surplusage, and furthermore their presence created confusion as to the meaning of the words "stating that fact" which appear later in the paragraph.

Section 305 (sec. 304 of the bill as it passed the Senate): In this section the prohibition against including poisonous or deleterious substances in food is changed to a declaration that the addition of any

such substance to food shall be deemed to be unsafe for the purposes of section 301 (a). This is not an actual change in policy, but this action was taken in order to avoid the possible claim that Congress was attempting to prohibit something which was not within its control.

Section 306 (sec. 305 of the bill as it passed the Senate): This section relates to emergency permit control, an extraordinary power to be exercised when food coming from a particular area is contaminated with micro-organisms and it is necessary to have some supervision of the situation until it clears up. The modifications made by the committee are entirely for the purpose of clarity and in order to more adequately safeguard the rights of persons who will be affected, by assuring them full protection of due process of law. The prohibition against a manufacturer, processor, or packer shipping from the particular area when the permit system is in effect has been changed to a prohibition against any person so shipping. This is not actually a change in substance, since the penalty provisions are this broad in their scope in the bill as it passed the Senate. It will be noted that in this section, as well as in several succeeding sections, the words "an unsuspended, valid" have been omitted. This relates to a requirement that the manufacturer, processor, or packer hold an unsuspended, valid permit. The words have been stricken out as being unnecessary. The committee is of the opinion that when the manufacturer, processor, or packer is required to have a permit issued by the Secretary that that necessarily means a permit which is valid and in effect, and laws passed by Congress are uniformly written upon this assumption.

Section 402 (a): Under this section as it passed the Senate a representation concerning the effect of a drug or device had to be supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion. The word "demonstrable" has been omitted. The Senate committee report indicated that the word was unnecessary and this committee struck it out on the ground that it added nothing to the provision. This same statement is applicable to the striking out of the same word in section 601 (a). This provision in section 402 (a), as in the case of section 601 (a), gives recognition to the right to distribute a drug or device in interstate commerce if the representation upon its labeling regarding its effect is supported by any sound evidence. In other words, it protects the manufacturer of the article in a case where there is an honest difference of opinion among competent authorities upon the question of the effect of the drug or device.

Section 402 (g): In this paragraph as it passed the Senate a drug or device is deemed to be misbranded unless its labeling bears such warnings in such form and manner as may be adequate. The committee changed this to require such warnings as are required by regulations prescribed by the Secretary; its reason for so doing being that it believed that the requirement of the Senate bill was so vague that it might be held to be invalid. Certainly the manufacturers of drugs and devices would have had grave difficulty in telling what warnings would have been "adequate" on the labeling of many products.

Section 402 (h): This paragraph as it passed the Senate relates to the requirement that certain drugs be packaged and labeled as prescribed in the official compendium in which they are named, unless

exempted under (1) of the section. The committee struck out the words "unless exempted under (1) of this section" as being surplusage.

Section 403 (a): This provision states that for the purposes of the act the term "antiseptic" shall be deemed to have the same meaning as the word "germicide." The justification for this provision is that the term "antiseptic" has more than one meaning, one of which is the same as "germicide", and it is undesirable to permit the word to be used under circumstances where it will be understood to mean the same as "germicide" without the person making representations with respect to it being held to that meaning.

Section 404 (sec. 403 of the bill as it passed the Senate): In this section the committee made a transposition of the words "and purposes of coloring only" for the purpose of clarity and with no change in meaning.

Section 601 (a): By this subsection as it was passed by the Senate it is declared that an advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is "false or misleading in a particular relevant to the purposes of this act regarding such food, drug, device, or cosmetic." The committee struck out the words "relevant to the purposes of this act" because it felt that by the retention of these words confusion and uncertainty would be caused.

It is difficult to understand in what situations an advertisement would be deemed to be false or misleading in a particular "relevant to the purposes of this act." The act relates to the adulteration and misbranding of food, drugs, devices, and cosmetics, and contains numerous procedural and implementing provisions to make those provisions effective. It also contains other provisions of a miscellaneous character. Then there is chapter VI relating to false advertisements in which the words above referred to appear. Nowhere in the act is there a statement of its purposes. Nothing helpful appears in the title of the bill, even if this could be considered. There is nothing in chapter VI which gives any idea as to when an advertisement would be relevant to the purposes of the act. Thus, it will be seen that if these words are included it would be necessary to show something which is so vague, as applied to an advertisement, as to be incapable of proof. In view of these considerations, the committee thought it necessary to eliminate these words. It is felt that the test as to whether an advertisement is false or misleading in any particular regarding a food, drug, device, or cosmetic is adequate, and it is substantially the same test to be found in the provisions relating to adulterated and misbranded food, drugs, devices, and cosmetics.

Section 601 (b): In this subsection the words "for the purposes of this act the" were struck out as being surplusage.

Section 602: This section, inserted by the committee, gives the Federal Trade Commission power to proceed, by the cease and desist order machinery provided in the Federal Trade Commission Act, against (1) the dissemination of false advertisement by the mails, or interstate commerce, for the purpose of inducing directly or indirectly the purchase of food, drugs, devices, or cosmetics; and (2) the dissemination of any false advertisement by any means for the purpose of inducing directly or indirectly the purchase of food, drugs, devices, or cosmetics in interstate commerce. Various conforming amendments have been made in the bill to carry out the purposes of this

new section, notably a change in the penalty section (section 706), which is modified so that the criminal and civil penalties will not apply in the case of false advertisements.

Section 702: The committee had several reasons for the omission of this section of the Senate bill. This section would have given to the district courts jurisdiction to restrain by injunction the enforcement of regulations, or to grant appropriate injunctive relief from any act or omission of the Secretary or his officers or employees, upon a showing that the regulation or the act or omission was unreasonable, arbitrary, or capricious, or not in accordance with the facts or law, and that the petitioner might suffer substantial damage by reason of the enforcement of the regulation or by reason of the act or omission. The committee was not aware of any precedent for such a provision. Insofar as it gave the court jurisdiction to decide whether the regulation, act, or omission was not in accordance with the facts, it was felt that this would constitute the imposition of a nonjudicial function upon the court. (See *Federal Radio Commission* v. *General Electric Co.* (281 U. S. 464).) Aside from this consideration the court would have been authorized to grant the relief if the petitioner could show that he "may suffer substantial damage." This seemed to the committee to be a radical departure from the ordinary principles of equity under which relief may be granted where there is no adequate remedy at law and the complaining person can show that he will suffer irreparable injury.

The committee felt that there was no reason to add to the existing remedies which are applicable in the case of administrative action under the many other acts passed by Congress. There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act enacted on June 14, 1934, as section 2074D of the Judicial Code (U. S. C., 1934 ed., title 28, sec. 400). Insofar as the court would, under the Senate bill, have been empowered to give relief in case a regulation or an act of the Secretary was unreasonable, arbitrary, or capricious, or not in accordance with law, this is merely the ordinary principle which the court applies in cases where an administrative official has exceeded his authority, and a person affected by an administrative official's action may always, whether in a criminal proceeding, equity proceeding, or any other proceeding, raise these issues. The provision of the Judicial Code above referred to gives the courts jurisdiction in actual controversies to declare rights and other legal relations of any interested party, and such a declaration has the force and effect of a final judgment or decree and is reviewable as such. This provision of the Judicial Code would apply to all kinds of disputes arising between parties or arising under legislation, but as stated in the report of the Judiciary Committee when it reported out the measure, "This form of preventive relief is distinguishable from curative relief in that the latter is incapable of redress until an injury has occurred or the contract broken." The remedy furnished seems to be peculiarly adapted to cases where the interests and rights of parties are affected by the acts of administrative officials. Prof. Edwin Borchard, of the Yale University School of Law, a recognized authority on this subject, stated in an article

appearing in the Law Week that it is in this field that the act will have its greatest usefulness. An example of its usefulness under the present act would be in the determination of the validity of the tolerances for added poisonous and deleterious substances fixed by regulations of the Secretary under section 305.

Section 703: This section was omitted because the committee felt that the establishment of the committees provided for was unnecessary.

Section 704: This section was omitted because the committee felt that it was unnecessary to specifically authorize the committees referred to, and furthermore that the authorization for the Secretary to accept plans for self-regulation would have given rise to confusion and uncertainty, particularly in view of the rather contradictory character of the proviso appearing at the end of the section.

Section 706 (section 704 of the bill as it passed the Senate): The proviso at the end of this section was transferred to section 703 (a) and somewhat modified, with no substantial change in policy.

Section 705 (section 707 of the bill as it passed the Senate): The introductory words of this section were modified with a view to making more certain of the validity of the section and in order to avoid the possibility that in acting under it the Secretary would have to show that he was acting for the purpose of safeguarding the public health and preventing deceit upon the purchasing public. It would seem that the more simple language substituted by the committee is preferable.

Section 709 (section 711 of the bill as it passed the Senate): This is the section containing the Bailey amendment, which appears as a proviso at the end of subsection (a). The committee inserted a substitute for the Bailey amendment, the first part of which it is believed makes no change in policy but will avoid the embarrassment which the Secretary of Agriculture would experience if he were to begin a libel for condemnation proceeding and for some reason it was found to be impossible to have the case decided on its merits. This might occur because the Bailey amendment as it passed the Senate provides that "not more than one seizure shall be instituted" in cases of alleged misbranding, etc. There are two substantive changes made by this committee. One is that multiple seizures would be permitted in cases where the Secretary has probable cause to believe that the misbranding is in a material respect false, misleading, or fraudulent. This will permit protection of the public against such nostrums as a brew of weeds labeled as a treatment for diabetes and against innumerable other cheats and frauds which at best rob the consumer's pocketbook, and at worst rob him of health or life through his mistaken reliance upon them while his disease progresses unchecked. With this change the seizure section will continue to function as a means of "arresting the bullet in flight before it claims its victim", although the administrative agency will have materially less latitude, in making multiple seizures, than it has had under the present law for the past 30 years. The other change is that the provision for removal for trial to the jurisdiction of the claimant's residence has been changed to permit removal to any district adjacent to the district of the claimant's principal place of business or to any

other district which may be agreed upon by stipulation between the parties.

Section 709 (f) (section 711 of the bill as it passed the Senate): This subsection was struck out because it seemed to the committee to be either unnecessary or else susceptible of the possible construction that it might give each district court authority to issue injunctions which would operate throughout the United States.

Changes in Existing Law

In compliance with paragraph 2a of rule XIII of the Rules of the House of Representatives, the Food and Drugs Act of June 30, 1906, as amended (with the exception of section 10A), which is repealed by the bill, effective 12 months after the date of enactment of the bill, is set forth below enclosed in black brackets.

[AN ACT For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such articles so adulterated or misbranded within the meaning of this act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry[2] of the Department of Agriculture, or under the direction and supervision of such bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug," as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food", as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contains terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the

provisions of this act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consist in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. That the term "misbranded", as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however*, That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of section three of this act.[3]

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound", "imitation", or "blend", as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this act may require to secure freedom from adulteration or misbranding.

Fifth. If it be canned food and falls below the standard of quality, condition, and/or fill of container, promulgated by the Secretary of Agriculture for such canned food and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. For the purposes of this paragraph the words canned food mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat food products which are subject to the provisions of the meat inspection act of March 4, 1907 (Thirty-fourth Statutes, page 1260), as amended, and except canned milk; the word class means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product. The Secretary of Agriculture is authorized to determine, establish, and promulgate, from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement, from time to time, as in his judgment may be necessary. In promulgating such standards and forms of statements and any alteration or modification thereof, the Secretary of Agriculture shall specify the date or dates when such standards shall become effective, or after which such statements shall be used, and shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statements shall be used. Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods.

SEC. 9. That no dealer shall be prosecuted under the provisions of this act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice

thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this act shall include the insular possessions of the United States. The word "person" as used in this act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies, and associations. When construing and enforcing the provisions of this act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

SEC. 13. That this act shall be in force and effect from and after the first day of January nineteen hundred and seven.]

ADDITIONAL VIEWS

The undersigned, members of the committee, in order that the membership of the House may be fully apprised of certain facts, submit the following additional views with respect to one of the most controversial features of the bill, namely, the question of whether the Federal Trade Commission should have jurisdiction over the false advertising features of the measure.

The committee changed the bill so as to give the Federal Trade Commission jurisdiction to prevent false advertising by means of the machinery provided by the Federal Trade Commission Act, namely, the issuance of orders addressed to the person complained of, ordering him to cease and desist from further committing the violation of the law. Under the bill as it passed the Senate disseminators of false advertisements of food, drugs, devices, and cosmetics would have been subject to a criminal or civil penalty, depending on the seriousness of the offense, and there was also the authority to obtain injunctions from the courts to prevent repetitious violations. The bill would not have been weakened so materially if these provisions had been retained and the Federal Trade Commission had been given authority to enforce them, but this was not the case. The criminal and civil penalty provisions have been struck out so far as false advertising is concerned, and the only enforcement machinery left is the cease-and-desist order as provided for in the Federal Trade Commission Act.

The simple fact is that the cease-and-desist-order machinery will not be effective to protect the public against false and misleading advertisements of food and drugs. This was demonstrated by exhibits before the subcommittee consisting of cease-and-desist orders against certain false advertising, and advertisements subsequently appearing over a period of years conveying essentially the same false representations prohibited by the orders. The Federal Trade Commission, acting under its authority to prevent unfair methods of competition, has been active against false advertising of food, drugs, devices, and cosmetics for a number of years. The frequency with which false advertisements have been disseminated for the same products previously covered by cease-and-desist orders, particularly in many of the lower-grade magazines and in the programs of certain radio stations, would seem to demonstrate the ineffectiveness of the cease-and-desist-order machinery in the case of false advertising. This is in no way a criticism of the Federal Trade Commission or its personnel, or of its diligence in enforcing the law under which it operates. No governmental agency has executed its functions more efficiently or more courageously. But it is a recognition of the fact that the method of procedure under which the Commission operates is subject to limitations which make it ill adapted to coping with the question of false advertising as it is conducted today.

An impartial appraisal of the effectiveness of the cease-and-desist order as contrasted with the machinery which would have been provided for in the bill as it passed the Senate, is contained in an authoritative work entitled "The Federal Trade Commission", by Gerard C. Henderson (1924). This book was published under the sponsorship of the Commonwealth fund, under the supervision of a legal research committee composed of some of the foremost legal authorities of the country, including Mr. Justice Cardozo and Mr. Justice Stone, now members of the Supreme Court. In Mr. Henderson's book the following statement appears:

> Looking at the matter from a more critical viewpoint, however, it becomes apparent that there are certain limitations in the powers of the Commission and certain obstacles in its procedure which impair its usefulness in some of the cases involved.
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> The second limitation which suggests itself, is that the Commission should not, except in special cases, institute proceedings where the practice in question falls within the scope of the Pure Food and Drugs Act, or of similar Federal legislation. The reason is that in such cases the law confers on the Department of Agriculture powers in many ways more effective than those of the Federal Trade Commission, and that the Department has a scientific personnel more competent to deal with the technical questions involved. The Food and Drugs Act of June 30, 1906, makes it unlawful to manufacture in any territory or in the District of Columbia, or to ship in interstate or foreign commerce, any article of food or any drug which is "adulterated or misbranded." The words "adulterated" and "misbranded" are comprehensively defined, and it is obvious that the definitions are framed with an eye to practical administration as well as scientific accuracy. They cover every conceivable case of misrepresentation as to the ingredients, strength, quality, or purity of a drug or food product, or (by an amendment added in 1912) as to its curative or therapeutic effect; and all cases of misbranding, including imitation of the distinctive name of another article, misstatement as to weight, measure, or numerical count, and misrepresentation as to the State, Territory, or county in which the article is produced. In its enforcement the act has great advantages over the cumbersome procedure of the Federal Trade Commission. One who violates the act may be criminally prosecuted, whereas the Federal Trade Commission can only order him to cease and desist, without even forfeiting the unlawful gains derived from the violation. An adulterated or misbranded article, if transported in violation of the law, may be libeled and forfeited in proper proceedings, whereas there is nothing in the Federal Trade Commission Act to prevent a dealer who has been ordered to cease from shipping certain misbranded articles in interstate commerce, from selling them to another dealer in the same State. The latter can ship them with immunity, so far as the Federal Trade Commission Act is concerned, until the Commission's procedure has again set in motion and a new order issued and confirmed by the Court. As a police measure the Food and Drugs Act is therefore vastly superior to the Trade Commission law.

It is not difficult to see how impossible it would be to effectively control false advertising of food, drugs, devices, and cosmetics through the cease and desist order machinery. A manufacturer, let us assume, puts an advertisement in a number of magazines and newspapers and broadcasts the advertisement over the radio. By this means the advertisement is quickly brought to the attention of millions of persons all over the country. The first move of the Federal Trade Commission would be to decide that it has reason to believe that the advertisement is false or misleading, and normally it only would be able to come to this conclusion after getting evidence and expert advice with regard to the matter from the technicians of the Food and Drugs Administration, unless a duplicate technical staff is to be established.

Having come to its conclusions, the Commission would serve upon the manufacturer a complaint and fix a date for a hearing which must be at least 30 days after the service of the complaint. At the proceeding the testimony would be reduced to writing and filed in the office of the Commission, and if the Commission found that the advertisement was false, it would have to make a report in writing in which it stated its findings as to the facts and would cause to be served upon the manufacturer an order requiring him to cease and desist from the dissemination of the false advertisement. If the manufacturer did not obey the order, the Commission could apply to the appropriate circuit court of appeals for the enforcement of its order. Notice would then be given to the manufacturer, and after a determination upon the questions involved the court would have power to affirm, modify, or set aside the Commission's order. Only at this point would it be necessary for the person complained against to stop disseminating the advertisement. During the time all of this procedure is being complied with, which in the ordinary course would involve the lapse of many months and sometimes many years, the manufacturer would be able to disseminate the particular advertisement freely and for a much longer period than he desired. Everyone is aware of the frequency with which advertisements are changed in modern times. Ordinarily they change from week to week. Even after the order became effective, the false information or claims contained in the advertisement would still repose in the minds of the millions of persons who had read or listened to or been told about the claims made in the advertisement. And the manufacturer will have reaped the benefits of the false advertisement without the slightest fear of a penalty of any kind.

From the foregoing statement it is obvious that the only effective means of preventing false advertisements is to enact provisions such as are in the Senate bill, under which the unscrupulous would be deterred from violation by a knowledge that risk of penalty is involved for each offense.

One of the arguments advanced in favor of the amendment to the Senate bill was that if the Food and Drug Administration were to enforce the advertising provisions there would be a duality of jurisdiction which would be unfortunate, and the implication was that this was without precedent. Actually there would have been nothing novel in leaving the bill as it was in the form passed by the Senate. A similar situation has existed for years between the Food and Drug Administration and the Federal Trade Commission. This is clearly demonstrated by the fact that in the field of adulteration and misbranding of food and drugs the Department of Agriculture has enforced the provisions of the Food and Drugs Act against adulteration and misbranding and the Federal Trade Commission has at the same time enforced the provisions of the Federal Trade Commission Act against adulteration and misbranding of articles, under the provisions relating to unfair competition.

On the other hand, there is real novelty in the change made in the Senate bill, since as a result of it there will be a division of authority in the enforcement of the act with regard to matters of misbranding, on the one hand, and false advertisements, on the other hand, in which identical representations are involved. This division of authority will inevitably cause confusion. It is certain that there will

arise differences of viewpoint between the two administrative agencies which will work hardship on manufacturers who are trying to comply with the law. Furthermore, proceedings by one agency will be seriously embarrassed when the defense shows that the language in issue is not objected to by the other agency. In every event the ultimate sufferer will be the public.

Another point has given rise to misunderstanding. It has been said that the bill as it passed the Senate is objectionable because it takes jurisdiction away from the Federal Trade Commission. It has been said that things should be left as they are. As a matter of fact that is what the bill as passed by the Senate did. Under the bill in that form the Federal Trade Commission would have been entirely undisturbed in its authority to proceed against any person for disseminating false advertisements where such action constituted an unfair method of competition. Placing with the Federal Trade Commission the authority to enforce the false-advertising provisions of the bill is an action entirely out of harmony with the philosophy of the Federal Trade Commission Act and the functions which have always been exercised by the Commission. The function of the Commission has been that of an umpire between parties in industry in disputes involving unfair methods of competition. This change in the Senate bill will require the Commission to reorient its viewpoint from that of the commercial umpire to that of the guardian of consumer welfare.

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